

§ 660.50

section until written notification of official release or notification that official release is no longer required is received from the Director, Center for Biologics Evaluation and Research.

[48 FR 20407, May 6, 1983, as amended at 49 FR 23834, June 8, 1984; 51 FR 15611, Apr. 25, 1986; 55 FR 11013 and 11014, Mar. 26, 1990]

Subpart F—Anti-Human Globulin

§ 660.50 Anti-Human Globulin.

(a) *Proper name and definition.* The proper name of this product shall be Anti-Human Globulin which shall consist of one or more antiglobulin antibodies identified in § 660.55(d).

(b) *Source.* The source of this product shall be either serum from animals immunized with one or more human serum globulins or protein-rich fluids derived from stable immunoglobulin-secreting cell lines maintained either in tissue cultures or in secondary hosts.

[50 FR 5579, Feb. 11, 1985, as amended at 65 FR 77499, Dec. 12, 2000]

§ 660.51 Processing.

(a) *Processing method.* (1) The processing method shall be one that has been shown to yield consistently a specific, potent final product, free of properties that would adversely affect the product for its intended use throughout its dating period.

(2) Anti-IgG, -C3d (polyspecific) reagents and anti-IgG products may be colored green.

(3) Only that material which has been fully processed, thoroughly mixed in a single vessel, and filtered shall constitute a lot. Each lot shall be identified by a lot number.

(4) A lot may be subdivided into sublots which shall be identified by the lot number to which has been added a distinctive prefix or suffix. If lots are to be subdivided, the manufacturer shall include this information in the license application. The manufacturer shall describe the test specifications to verify that each subplot is identical to other sublots of the lot.

(b) *Final containers and dropper assemblies.* (1) Final containers and dropper assemblies shall be clean.

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(2) Final containers and dropper pipettes shall be colorless and sufficiently transparent to permit observation of the contents for presence of particulate matter or increased turbidity.

(c) *Date of manufacture.* The date of manufacture shall be the date the manufacturer begins the last entire group of potency tests.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 65 FR 77499, Dec. 12, 2000; 67 FR 9587, Mar. 4, 2002]

§ 660.52 Reference preparations.

Reference Anti-Human Globulin preparations shall be obtained from the Center for Biologics Evaluation and Research (HFB-221), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, and shall be used as described in the accompanying package insert for determining the potency of Anti-Human Globulin.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11015, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002]

§ 660.53 Controls for serological procedures.

Red blood cells sensitized with complement shall be tested with appropriate positive and negative control antisera. All tests shall be performed in accordance with serological testing procedures approved by the Director, Center for Biologics Evaluation and Research (HFB-1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11014, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002]

§ 660.54 Potency tests, specificity tests, tests for heterospecific antibodies, and additional tests for nonspecific properties.

The following tests shall be performed using test procedures approved by the Director, Center for Biologics Evaluation and Research (HFB-1), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892:

(a) Potency tests for determining anti-IgG and anti-complement activity.

(b) Specificity tests, tests for heterospecific antibodies, and additional tests for nonspecific properties.

[50 FR 5579, Feb. 11, 1985, as amended at 50 FR 16474, Apr. 26, 1985; 51 FR 15611, Apr. 25, 1986; 55 FR 11014, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002]

§ 660.55 Labeling.

In addition to the applicable labeling requirements of §§ 610.62 through 610.65 and § 809.10 of this chapter, and in lieu of the requirements in §§ 610.60 and 610.61 of this chapter, the following requirements shall be met:

(a) *Final container label*—(1) *Color coding*. The main panel of the final container label of all Anti-IgG, -C3d (polyspecific) reagents shall be white or colorless and printing shall be solid dark contrasting lettering. The main panel of the final container label of all other Anti-Human Globulin reagents shall be black with solid white lettering. A logo or company name may be placed on the final container label, however, the logo or company name shall be located along the bottom or end of the label, outside of the main panel.

(2) *Required information*. The proper name “Anti-Human Globulin” need not appear on the final container label provided the final container is distributed in a package and the package label bears the proper name. The final container label shall bear the following information:

(i) Name of the antibody or antibodies present as set forth in paragraph (d) of this section. Anti-Human Globulin may contain one or more antibodies to either immunoglobulins or complement components but the name of each significant antibody must appear on the final container label (e.g., anti-C3b, -C3d, -C4d). The final container labels of polyspecific Anti-Human Globulin are not required to identify antibody specificities other than anti-IgG and anti-C3d but the reactivity of the Anti-Human Globulin shall be accurately described in the package insert.

(ii) Name, address, and license number of the manufacturer.

(iii) Lot number, including any subplot designations.

(iv) Expiration date.

(v) Source of the product.

(vi) Recommended storage temperature in degrees Celsius.

(vii) Volume of product.

(viii) Appropriate cautionary statement if the Anti-Human Globulin is not polyspecific. For example, “DOES NOT CONTAIN ANTIBODIES TO IMMUNOGLOBULINS” or “DOES NOT CONTAIN ANTIBODIES TO COMPLEMENT COMPONENTS.”

(ix) If the final container is not enclosed in a package, all items required for a package label shall appear on the container label.

(3) *Lettering size*. The type size for the designation of the specific antibody on the label of a final container shall be not less than 12 point, unless otherwise approved by the Director, Center for Biologics Evaluation and Research (HFB-1). The prefix anti- and other parts of the name such as polyspecific may appear in smaller type.

(4) *Visual inspection*. When the label has been affixed to the final container, a sufficient area of the container shall remain uncovered for its full length or for no less than 5 millimeters of the lower circumference to permit inspection of the contents.

(b) *Package label*. The following items shall appear either on the package label or on the final container label if see-through packaging is used:

(1) Proper name of the product, and the name of the antibody or antibodies as listed in paragraph (d) of this section.

(2) Name, address (including zip code), and license number of the manufacturer.

(3) Lot number, including any subplot designations.

(4) Expiration date.

(5) Preservative(s) used and its concentration.

(6) Number of containers, if more than one.

(7) Recommended storage temperature in degrees Celsius.

(8) Source of the product.

(9) Reference to enclosed package insert.

(10) The statement: “For In Vitro Diagnostic Use.”

(11) The statement: “Meets FDA Potency Requirements.”